

## REMARKS

The Office Action mailed 11 February 2004, has been received and its contents carefully noted. Claims 1-8 were pending. Claims 3 and 8 were withdrawn from consideration. Claims 1, 2 and 4-7 were rejected. By this amendment, claims 3 and 8 have been canceled and claim 6 has been amended to change the abbreviation "CF" to "colonization factor". The original claims have been appropriately renumbered. New claims 9-13 have been added. Support may be found throughout the parent specifications and claims as originally filed. For example, see the second full paragraph on page 5 and the originally filed claims of U.S. Patent Application No. 09/070,802. Also, see the originally filed claims of U.S. Patent Application No. 09/580,385. No statutory new matter has been added. Entry of the amendment and reconsideration are respectfully requested.

### Priority Date of Claims

The Examiner requested that Applicants point out how the present case differs from the parent to properly apply the correct priority date to the claims.

Applicants respectfully submit that the specifications and claims of the present case, 09/942,974, the parent case, 09/580,385, and the grandparent case, 09/070,802, as originally filed differ in the placement and arrangement of the verbage and that the substantive disclosures of the three applications do not differ. Specifically, throughout the specification and claims of the present, parent, and grandparent applications as originally filed, it is disclosed that:

- 1) The colonization factor is obtained;
- 2) The colonization factor is solubilized by dissolving the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol;
- 3) A solution of volatile acid is added to the solubilized colonization factor to obtain a product;
- 4) The product is subjected to mass spectrometry to determine the mass of the colonization factor; and
- 5) The determined mass is compared with the mass of at least one known colonization factor.

Also it is disclosed throughout the specification and claims of the present, parent, and grandparent applications as originally filed that:

6. The colonization factor is dissolved in 1,1,1,3,3,3-hexafluoro-2-propanol to a concentration of about 10  $\mu$ M to about 20  $\mu$ M;
7. The volatile acid can be acetic acid;
8. The acetic acid solution is added to bring the concentration to 5  $\mu$ M to 10  $\mu$ M; and
9. The product is scanned m/z 1400 to m/z 2500.

Therefore, Applicants respectfully point out that the priority date of the present invention as claimed is properly 1 May 1998.

#### **Rejection under 35 U.S.C. 112, second paragraph**

The Examiner rejected the claims as being indefinite for improper numbering.

The claims as amended herein are correctly renumbered. Therefore, the rejection under 35 U.S.C. 112, second paragraph should properly be withdrawn.

#### **Abstract under 37 C.F.R. 1.72(b)**

The Examiner required that an abstract according to 37 C.F.R. 1.72(b) be submitted.

Applicants submit herewith an abstract. Applicants note that the abstract does not add any statutory new matter.

#### **Rejection under 35 U.S.C. 102(b)**

The Examiner rejected claims 1, 2 and 4-7 under 35 U.S.C. 102(b) as being anticipated by an abstract for ASM General Meeting entitled “Absolute Molecular Weight Determination of E. coli Fimbrial Major Subunits” (1993) by Cassels et al. Specifically, the Examiner deemed that “purified fimbriae were suspended in 50% hexafluoroisopropanol and 1% acetic acid”.

Applicants respectfully submit that the abstract does not teach or suggest the present invention as claimed. Specifically, the abstract merely states “purified fimbriae were suspended in 50% hexafluoroisopropanol and 1% acetic acid and electrosprayed” (emphasis added). The present invention as claimed requires that the colonization factors are first solubilized in 1,1,1,3,3,3-hexafluoro-2-propanol and then acetic acid is added. The abstract does not indicate that the fimbriae are suspended in hexafluoroisopropanol in a first step then acetic acid is added in a second distinct step. Instead, the abstract uses the word “and” which indicates that that purified fimbriae were suspended in a single solution of hexafluoroisopropanol and acetic acid as

a single step. Clearly, the abstract does not teach the criticality of the two distinct steps in the specific order of first solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol and then second adding acetic acid.

In support of the above, Applicants submit herewith declarations. The first declaration is by Frederick J. Cassels, Ph.D. (Cassels Declaration). The second declaration is by Ryan T. Ranallo, Ph.D. (Ranallo Declaration).

As provided in the Cassels Declaration, first dissolving the colonization factor in acetic acid and then adding hexafluoropropanol does not result in observable signals for the 15055 and 15877 protein peaks. Conversely, first dissolving the colonization factor in hexafluoropropanol and then adding acetic acid provides observable signals for the 15055 and 15877 protein peaks. Therefore, solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol first and then adding acetic acid second is critical to the claimed invention for identifying colonization factors.

As provided in the Ranallo Declaration, a person of ordinary skill in the art would not understand that the abstract teaches or suggests solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol first and then adding acetic acid second. As declared by Ranallo, a person of ordinary skill in the art, would not understand after reading the abstract, that the order of solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol first and then adding acetic acid second is critical to obtaining certain protein peaks that are necessary for identifying certain colonization factors.

Applicants respectfully submit that the order of solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol first and then adding acetic acid second is critical for identifying colonization factors via mass spectrometry and that the abstract does not teach or suggest the criticality of the order of steps. Therefore, the present invention as claimed is novel and nonobvious and the rejection under 35 U.S.C. 102(b) should properly be withdrawn.

*Use of “comprising the following steps in the following order”.*

Applicants note the Examiner’s concerns regarding the use of “comprising” rather than “consisting of”. Applicants respectfully point out that the use of “comprising” in the phrase “comprising the following steps in the following order” indicate that other steps may be included; however, the steps must be conducted in order as listed in the claims. Thus, there may be steps included before the steps listed in the claims or there may be steps included after the

steps listed in the claims. Alternatively, there may be steps included in between the steps as listed in the claims. In any event, the steps listed in the claims must be conducted in order, i.e. first, solubilizing the colonization factor in 1,1,1,3,3,3-hexafluoro-2-propanol; then second, adding a solution of volatile acid to the solubilized colonization factor to obtain a product; then third, subjecting the product to mass spectrometry to determine the mass of the colonization factor; and then comparing the mass determined previously with the mass of at least one known colonization factor.

Applicants respectfully point out that “consisting of” language is not necessary to indicate steps in a certain order and that the phrase “comprising the following steps in the following order” is more than adequate to require steps in a certain order.

### **Request for Interview**

Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

## CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. **210-380**, referencing Attorney Docket No. **034047.034.2 (WRAIR 97-30B)**.

Respectfully submitted,

  
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